K090962

510(k) SUMMARY

Title: **Quanta System Cyber Surgical Laser Family**

JUN 19 2009

Submitter:
Quanta System SpA
via IV Novembre,116
21058 Solbiate
Olona VA / Italy

Contact:
Dr. Isabella Carrer
Medical Division Manager

Date Prepared: June 11, 2008

Device Trade Name: Quanta System Cyber Surgical Laser Family

Common Name: Laser surgical instrument for use in general surgery and dermatology

Classification Name: Instrument, surgical, powered, laser

Predicate Devices:
- AllMed System **Revolix 120 Laser System (K070476);**
- Laserscope **GreenLight HPS Series Surgical Laser and System Accessories (K062719);**

Intended Use / Indications for Use:

532nm Applications:

The Cyber Surgical Laser Family and Accessories are intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

General Surgery:
Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft tissue as well as in Endoscopic (e.g. laparoscopic) or open surgeries.

Gastroenterology:
Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including

squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

Gynecology:
Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: Endometriosis; Cervical, vulvar, and vaginal intraepitheal neoplasia; Condyloma Acuminata; Uterine Septum; Intrauterine adhesions; Submucosal fibroids.

Head and Neck/Otorhinolaryngology (ENT):
Tissue incision, excision, ablation, and vessel hemostasis.

Neurosurgery:
Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

Opthamology:
Post-vitrectomy endophotocoagulation of the retina.

Plastic Surgery:
Vaporizing, Coagulating, Incising, Excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery:
Percutaneous lumbar diskectomy. Thoracic Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology:
Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: Bladder; Urethral & Ureteral Tumors; Condylomas; Lesions of external genitalia; Urethral & penile Hemangioma; Urethral Strictures; Bladder Neck Obstructions; and, when used at 532nm it is intended to hemostatically vaporize prostate tissue of men suffering from benign prostate hyperplasia/hypoplasia (BPH). The device is not intended to treat prostate cancer.

2.01µm Applications:

The Cyber Surgical Laser Family and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, General Surgery, and Arthroscopy

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral
- Tumors.
- Ablation of Benign Prostatic Hypertrophy (BHP),
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostrate (HoLRP)
- Laser Enuculeation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi

- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitas
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection,
ablation, vaporization, coagulation and hemostasis)

- Intra-uterine treatment of submucous fibroids, benign endometrial polyps,
- and uterine septum by incision, excision, ablation and or vessel
- coagulation
- Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation,
vaporization, coagulation and hemostasis of soft tissue) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy

- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesion
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial Nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of Decubitus Ulcer
- Hemorrhoids
- Debridement of Statis Ulcer
- Biopsy

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and
cartilaginous tissue)

- Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal
- Surgery including
- Percutaneous Laser Disc Decompression/Discectomy
- Foraminoplasty
- Ablation and coagulation of soft vascular and non vascular tissue in
- minimally invasive spinal surgery.

The Cyber Surgical Laser Family is a surgical laser instrument for use in general surgery and dermatology. The Cyber Surgical Laser Family includes 3 models:

Models	Wavelength	Laser Power
Cyber Green	532nm	120W
Cyber Tm	2.01µm	120W
Cyber Green/Tm	532nm and 2.01µm	120W@532nm; 120W@2.01µm

- Model **Cyber Green** is intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: General Surgery, Gastroenterology, Gynecology, Head and Neck/Otorhinolaryngology (ENT), Neurosurgery, Opthamology, Plastic Surgery, Spinal Surgery and Urology.

- Model **Cyber Tm** is intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Gynecology, ENT, General Surgery and Arthroscopy

- Model **Cyber Green/Tm** is a combination of Cyber Green and Cyber Tm. The indication for use is the same of Cyber Green and Cyber Tm.

Technological Characteristics:

The device consists of a rack that houses the cooling units (2 chillers), the laser source and the power

supply. Above the rack, into a cover-proof light, the laser head and optical bench with the beam delivery optics and the power meter are housed.
The Cyber Green includes a Q-Switch Nd:YAG frequency doubled Laser Source (KTP) that emit a pulsed laser light at 532nm with power adjustable from 0.5 to 120W.
The Cyber Tm includes a Tm:YAG Laser Source that emit a Cw laser light at 2.01µm wavelength with power adjustable from 5 to 120W.
The **Cyber Green/Tm** includes a Q-Switch Nd:YAG frequency doubled Laser Source (KTP) that emit a pulsed laser light at 532nm with power adjustable from 0.5 to 120W, and a Tm:YAG Laser Source that emit a Cw laser light at 2.01µm wavelength with power adjustable from 5 to 120W.
An SMA connector allows the connection of an optical fiber in which the main beam and the 650nm aiming beam are launched. Sidefire fibers (600µm) and bare fibers (200, 400 and 600µm) are available for both laser source.
The emergency red push button , the key-switch and the operation status led are housed in the front part of the system.
The footswitch connector is housed in the back side of the system. A metal door closes the lower rack.
On the back panel are housed the magneto-thermal switch (circuit braker), the line cable with IEC309 /32A plug and a safety interlock connector. The rear panel also contains the power supply and chillers outlet grids cooling .
The device is controlled by a touch-screen PC mounted on a oriental arm.

Performance Data None

Substantial Equivalence: The Quanta System Cyber Surgical Laser Family is as safe and effective as the predicate devices. The Cyber Surgical Laser Family has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Cyber Surgical Laser Family and its predicate devices raise no new issues of safety or effectiveness. Thus, the Cyber Surgical Laser Family is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

Quanta System, S.P.A.
% Regulatory Technology Services, LLC
Mr. Mark Job
Reviewer
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K090962
Trade/Device Name: Cyber Surgical Laser Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and In Dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 8, 2009
Received: June 10, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter D. Rumm 2
Rumm DP

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090962

Device Name: **Cyber Surgical Laser Family**

Indications for Use:

532nm Applications:

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General Surgery:
Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft tissue as well as in Endoscopic (e.g. laparoscopic) or open surgeries.

Gastroenterology:
Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Espohagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

Gynecology:
Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: Endometriosis; Cervical, vulvar, and vaginal intraepitheal neoplasia; Condyloma Acuminata; Uterine Septum; Intrauterine adhesions; Submucosal fibroids.

Head and Neck/Otorhinolaryngology (ENT):
Tissue incision, excision, ablation, and vessel hemostasis.

Neurosurgery:
Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

Opthamology:
Post-vitrectomy endophotocoagulation of the retina.

Plastic Surgery:
Vaporizing, Coagulating, Incising, Excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery:

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Percutaneous lumbar diskectomy. Thoracic Surgery: Vaporizing, Coagulating, Incising, Excising, Debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology:
Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: Bladder; Urethral & Ureteral Tumors; Condylomas; Lesions of external genitalia; Urethral & penile Hemangioma; Urethral Strictures; Bladder Neck Obstructions; and, when used at 532nm it is intended to hemostatically vaporize prostate tissue of men suffering from benign prostate hyperplasia/hypoplasia (BPH). The device is not intended to treat prostate cancer.

2.01µm Applications:

The Cyber Surgical Laser Family and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, General Surgery, and Arthroscopy

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral
- Tumors.
- Ablation of Benign Prostatic Hypertrophy (BHP),
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostrate (HoLRP)
- Laser Enuculeation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy

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- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitas
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis)

- Intra-uterine treatment of submucous fibroids, benign endometrial polyps,
- and uterine septum by incision, excision, ablation and or vessel
- coagulation
- Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy

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- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

General Surnqery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesion
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial Nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of Decubitus Ulcer
- Hemorrhoids
- Debridement of Statis Ulcer
- Biopsy

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Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

- Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal
- Surgery including
- Percutaneous Laser Disc Decompression/Discectomy
- Foraminoplasty

- Ablation and coagulation of soft vascular and non vascular tissue in
- minimally invasive spinal surgery.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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